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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/712,265 | 11/14/2003 | Nadine Ferdman Burton | 051438-5002 | 8062 |
| 9629 | 7590 | 07/27/2007 | EXAMINER | |
| MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 | | | ZALUKAEVA, TATYANA | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3761 | | |
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| | | 07/27/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/712,265 | BURTON ET AL. |
| | Examiner | Art Unit |
| | Tatyana Zalukaeva | 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 September 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9 and 13-28 is/are rejected.
 7) Claim(s) 10-12 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The indicated allowability of claims 1-15 and 17-28 is withdrawn in view of the newly discovered reference(s) to Nettekoven (U.S. 5,496,270). Rejections based on the newly cited reference(s) follow.
2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: originally filed claims 13 and 14 recite "sealing receptacle" The specification lack such recitation.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 5, 9, 15-17, 20, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nettekoven (U.S. 5,496,270).

With respect to claim 1, Nettekoven discloses a medical vacuum aspiration device (column 1, lines 4-6) suction-irrigation device for use in performing medical procedures comprising: an aspiration cylinder (suction coupling tube 25 shown in Figures 1 and 2 coupled to a conventional source of suction (column 4, lines 3-7); and a valve (housing 11). The valve comprises: a removable fluid conduit (disposable insert 19, consisting of internally connected tubes 16, 17 and 18 shown in Figure 3) having a first end (end 17c) for attaching to the aspiration cylinder (tube 25) and a second end (18b) for attaching to a cannula (surgical member 23 shown in Figures 1 and 2 for insertion into a patient's interior column 3, lines 60-63); a valve housing (11) having at least first (12) and second (13) housing portions that define a cavity (semi-circular

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spaces 13a, 13b, 13c, 14a, 14b and 14c) for removably holding at least a portion of the fluid conduit (disposable insert) 19 discarded (column 6, line 62-63); a hinge (hinge 15 shown in Figure 1 and disclosed in column 1, lines 15-16) about which the first housing portion pivots relative to the second housing portion (Figures 1 and 2 and column 1, line 15); means for removably attaching the first housing portion to the second housing portion (flexible tang 26 shown in Figure 1 and disclosed in column 4, lines 21-30); and an actuator (button 27), coupled to the valve housing, that selectively compress a portion of the fluid conduit to open and close a suction path defined by the fluid conduit (column 6, lines 9-32).

With regard to claim 9, the first and second housing portions engage the fluid conduit (19) to restrain movement of the fluid conduit relative to the housing (column 3, lines 12-19) circular openings 13a-c, 14a-c in housing 11 tightly enclose insert 19).

With regard to claim 15, Nettekoven discloses a medical vacuum aspiration device (column 1, lines 4-6) suction-irrigation device for use in performing medical procedures comprising: an aspiration cylinder (suction coupling tube 25 shown in Figures 1 and 2 coupled to a conventional source of suction) column 4, lines 3-7); a valve (housing 11) adapted for fluid communication with the aspiration cylinder (Figures 1 and 2), the valve including first (12) and second housing portions (13), each including inner and outer walls (Figure 1); a releasable connector (flexible tang 26 shown in Figure 1 and disclosed in column 4, lines 21-30) joining the first housing portion to the second housing portion such that the first housing portion and the second housing portion

cooperate to define a housing (11) having first and second open ends (proximal end 14 and unnumbered distal end shown in Figure 1) and a cavity defined by the inner walls (semi-circular spaces 13a, 13b, 13c, 14a, 14b and 14c) extending between the first and second open ends (Figure 6); a hinge (hinge 15 shown in Figure 1 and disclosed in column 1, lines 15-16) about which the first housing portion pivots relative to the second housing portion (Figures 1 and 2 and column 1, line 15); a fluid conduit (disposable insert 19, consisting of internally connected tubes 16, 17 and 18 shown in Figure 3) retained in the cavity when the first and second housing portions are joined by the releasable connector (Figure 2), and exposed for removal from the cavity when the releasable connector is released (Figure 1), the fluid conduit including a flexible portion (column 1, lines 19-23); and at least one conduit clamp (cam follower 31 shown in Figures 5 and 10) movably mounted on one of the housing portions and engagable with the flexible conduit portion to compress the conduit portion (column 6, lines 9-32).

With regard to claims 16- 17, 20, 25 and 27, Nettekoven discloses the following:

Claims 16, 17: the hinge comprises a living hinge (hinge 15 consisting of a flexure bearing with no moving parts).

Claim 20: the releasable connector is a releasable latch (tang 26 described in column 4, lines 21-30).

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Claim 25: the valve is a plastic that can be sterilized (plastic cross-hatching shown in Figure 5 and sterilization disclosed in column 6, lines 59-65).

Claim 27: fluid conduit comprises silicone (column 3, lines 19-23, particularly lines 22-23).

5. Claims 2-4 and 6-8, 18, 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Nettekoven. While Nettekoven discloses the aspiration device as instantly claimed, he does not disclose that the first and second housing portions comprise a single piece unit and that the fluid conduit and the receptacle comprise a single piece unit, as per claims 2 and 6. However, in light of *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); The resilient material is used in Nettekoven as a material for the housing, therefore, it would have been within the skill of those skilled in the art to utilize the polypropylene, as a resilient plastic conventionally utilized as a material in medical aspiration devices. With regard to claims 7 and 8, Nettekoven discloses the use of silicone rubber in col. 3, lines 21-23. With regard to claims 18, 19 while Nettekoven discloses a single hinge, the instant claim calls for two of them. It is well established in the art that the duplication of parts is within the skill of those skilled in the art, and as such is obvious.

6. Claims 13, 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noelle (U.S. 4,909,792) in combination with Nettekoven.

Nettekoven discloses a valve for controlling suction of the aspiration irrigation device; the valve essentially comprises the structural elements as claimed. Sealing receptacle, as per instant claims 13, 14 is not specifically disclosed in Nettekoven. Norelli discloses gasket/sealing receptacle 134 that forms a fluid-tight seal between the valve housing portions of the fluid conduit and is integrally formed of the conduit (column 6, lines 50-61 and figure 10). It will be obvious to those skilled in the art at the time the invention was made to utilize the sealing elements as described in Norelli in the device of Nettekoven in order to form a fluid tight seal between the aspirator cylinder 300 and the fluid conduit.

With regard to claim 28, Nettekoven does not specify the presence of the aspiration syringe and cannula. However, surgical member 23 is a cannula, and the use of a syringe is conventional and routinely used in the art, such as disclosed in Norelli .

Norelli discloses medical device/syringe that creates a vacuum within the syringe by withdrawing the plunger from the syringe body (column 4, lines 5-11) with removable fluid conduit 10 having a first end for attaching to an aspiration cylinder/plunger end (figure 6) and a second end for attaching to a needle/cannula 12 (figure 3); a safety device/valve housing 50 for any type of medical purpose (column 5, lines 43-58) having semi-cylindrical jaws/first and second housing portions 52,54 that define a cavity for removably holding at least a portion of conduit 10 (column 4, lines 56-65 and figures 3 and 5); each jaw/housing portion is connected to the barrel 56 by a hinge 58 and 60, respectively to form a single-piece unit (column 4, lines 60-65). Based on the similarity

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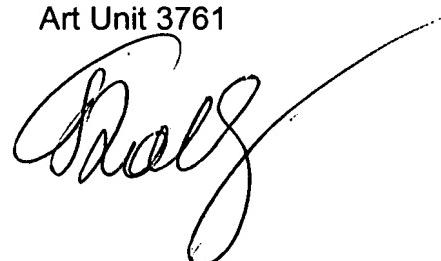
of devices and the problem to be solved it would have been obvious to those skilled in the art that the device of Nettekoven is connected to a cannula and syringe in order to perform the intended function.

Allowable Subject Matter

7. Claims 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art references do not disclose or suggest the cap that connects the first and second housing portions

Any inquiry concerning this communication should be directed to Tatyana Zalukaeva at telephone number (571) 272-1115.

Tatyana Zalukaeva
SPE
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A handwritten signature in black ink, appearing to read "Tatyana Zalukaeva".